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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/781,023	02/09/2001	Neil H. Riordan	RIORD.006A	1580

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EXAMINER	
YU, MISOOK	

ART UNIT	PAPER NUMBER
1642	12

DATE MAILED: 05/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/781,023	Applicant(s) RIORDAN, NEIL H.	
	Examiner MISOOK YU, Ph.D.	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 February 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35 and 70-79* is/are pending in the application.

4a) Of the above claim(s) *35* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-34, and 70-79* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Receipt of the Amendment filed on 2-25-2003 is acknowledged.

Election/Restrictions

Claim 35 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b). Claims 1-35 and 70-79 are pending. Claims 1-34, and 70-79 are examined on merits.

Specification

The objection of the amendment under 35 U.S.C. 132 is **withdrawn** in view of amendment.

Claim Rejections - 35 USC § 112

Rejection of claims 1-34, 70-79 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention **is withdrawn** because upon reconsideration the issues raised here are more or less issues of enablement rather than the boundary of one's property.

Claims 70-79 **remain rejected** for reason of record under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had **possession** of the claimed invention. Applicant argues that many other antigen presenting cells are well known in the art but this argument is not persuasive because the argument is not commensurate with the scope of the claims. Although other antigen presenting cells are known in the art, the art does not teach any antigen presenting cells when co-cultured with urine isolate and then given to patients along with urine isolate can treat cancer or cachexia patients.

Claims 1-19 and 70-79 **remain rejected** for reason of record under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to **enable** one skilled in the art to which it pertains, or with

which it is most nearly connected, to make and/or use the invention. Applicant's arguments and other responses have been fully considered but found unpersuasive because the specification lacks adequate disclosure to enable one skilled in the art to make/use the claimed invention without resorting to undue experimentation. Applicant has not argued the Office's conclusion "*One cannot extrapolate the teachings of the specification to the claimed invention because the specification does not teach method of cancer treatment using the methods of claims 1-19 and 70-79.*" See page 5 of the previous Office action.

The anecdotes were mentioned in the previous Office action for two main reasons: to direct applicant's attention that the method of claims 70-79 and the method of the anecdotes are different methods, and also to make a point that even if the instant claims 70-79 **were** drawn to the method used in the examples, the specification does not provides adequate disclosure to enable one skilled in the art to make/use the claimed invention without resorting to undue experimentation. First, since the anecdotes do not provide any control at all for such claim as cancer treatment, it is not clear whether anecdotes presented as evidence in the instant specification is due to miracle as reported to be happened before according to Eldo (1997) or any other causes such as chemotherapy and other conventional cancer treatment the patients might have had received other than the treatment, or result of the treatment. Second, the specification does not provide enough guidance about how the product(s) are prepared and what is the dose range for the products in order to be effective in treating cancer or cachexia. Compare the cancer vaccination guidance provided by Greiger et al (published in 2001, the same year the instant application was filed) at the Material and Methods section and Table 1 to the guidance in the instant specification. It is well known in the art that cancer treatment is unpredictable.

Applicant argues that the specification gives several examples of cancer status being improved. The examples in the specification have been considered. However, the examples used a different treatment method from the method of these claims. The claimed method involves administering urine isolate, alone or in combination with antigen-presenting cells (APCs). The examples in the specification administered urine-

treated APCs; the APCs were cocultured with urine isolate and washed, thereby removing the urine isolate before the cells were administered. Therefore the examples in the specification involve a different treatment. In addition, it is noted that the working examples do not teach details such as the amount of APCs administered to each patient in the treatment. For these reasons the working examples do not provide guidance for the invention being examined in this application.

Applicant argues that the enablement rejection is a proxy for a utility rejection, and argues that the invention meets the requirements for utility. Both utility and enablement do involve the issue of the application's disclosure of how to use the invention. But arguing that the invention meets the requirements of utility does not resolve the issue of whether undue experimentation would be require to practice the disclosed use. In the cancer treatment art, those skilled in the art generally demonstrate a skeptical response to anecdotal reports of success in uncontrolled studies with small numbers of patients, see as evidence the reviews by Herbert (1986, Cancer; 58, 8 Suppl, pages 1930-41, abstract only) and by Green (1982, Controlled Clinical Trials; 3, pages 189-98, abstract only). These references are not cited to suggest that the examiner thinks the claimed invention is somehow fraudulent, but to show that those skilled in the art would still question the efficacy of a treatment even after viewing evidence similar to the results presented in the specification. Considering the limited guidance in the specification, the state of the art, the unpredictability of effective cancer treatment, the documented skepticism of those in the art regarding the type of evidence provided in the specification, and the absence of working examples for the invention claimed, it is maintained that undue experimentation would be required to practice the invention as claimed.

Claims 20-34 remain rejected for reason of record under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to **enable** one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicant argues that the specification at page 5 line 28 to page 28 says urine contains cachexia-inducing

molecules and Example 1 provides an example. However, this argument is not persuasive because the method used in Example 1 is different than the method claimed. Instant claims 20-34 uses urine isolate and Examples 1 uses something else.

Since the previously cited review article indicates that cachexia is multi-faceted, complex problem that cannot be treated with imunogen alone, and the contradictory teachings of Cariuk et al, i.e. cancer antigen found in urine causes cachexia instead of helping to gain weight, and the specification provides insufficient guidance and provides no working examples (other than notoriously difficult to follow anecdote using a different method than the method of claims 20-34) or any other evidence which would provide guidance to one skilled in the art, it is maintained that one in skilled in the art would have reason to question the efficacy of the claimed method in treatment of cachexia with a reasonable expectation of success.

Claim Rejections - 35 USC § 103

All of the rejection under 35 U.S.C. 103(a) are withdrawn because upon reconsidering it is determined that one in the art would not be motivated to develop cancer treatment requiring huge amount of resources based on the medical hypothesis, not a scientific data of Eldo alone.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 703-308-2454. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Misook Yu
May 19, 2003

MARY E. MOSHER
PRIMARY EXAMINER
GROUP ~~1800~~ 1600